Remarks

Applicant gratefully acknowledges the Examiner's indication that all prior objections, not reiterated in the December 30, 2002 office letter are withdrawn in light of Applicant's amendment to the claims.

The Examiner has maintained his rejections of Claims 1-8, 10-21, 23, 25-29, 32, 39 and 40 under 35 U.S.C.§ 103(a) primarily in view of May (GB 2,204,398) in light of U.S. Patent No. 5,141,877 to Massaro. Applicant respectfully requests that the Examiner reconsider his rejections in light of the following comments.

Claims 1, and 13 require a conjugate pad, which is not disclosed, taught or suggested by May, or Massaro.

The Examiner states that such a pad is taught throughout the teachings of May, and supports this position by stating that although the zone or pad bearing the labeled reagent is not designed as a conjugate pad, it is seen to be the same with the instant conjugate pad because they both serve the same function and carry the same reagent. Although the Examiner has correctly stated that the zone of May bearing the labeled reagent is not designed as a conjugate pad, it is however, respectfully submitted that the Examiner incorrectly interpreted May as teaching a conjugate pad which May does not. The reference device in May does not have a zone **or** pad, it **only** has a zone 12 extending across the entire width of the strip, See FIG.1 of May. Nowhere does May suggest the use of a pad at the upstream portion of the strip. Rather, May discloses zone 12 (within the test strip) loaded with a first antibody bearing a visible ("direct") label (e.g. coloured latex particle, dye sol or gold sol). This antibody migrates through the strip with liquid sample. Fig. 1 clearly shows zone 12 as an area of the strip loaded with a first antibody. May differs from claims 1 and 13 in that the reagent only binds with the analyte within the strip itself.

In contrast, Applicant's claims 1 and 13 require, among other things, two separate components, i.e. a conjugate pad, and a chromatographic test strip. The conjugate pad being readily disposed upon the chromatographic test strip. The conjugate pad further contains the mobile specific binding partner. Thus, when liquid sample such as urine passes into the conjugate pad of Applicant's invention, the chromogenic mobile specific binding partner or reagent mixes with the liquid sample and immediately begins to react with analyte within the conjugate pad. Only after this first opportunity to react in the conjugate pad occurs, will the liquid sample mixture pass into the test strip. Claims 1 and 13 are different from May because May does not teach, or reasonably suggest a device, which allows for the mixture of the reagent and analyte prior to entry into the test strip. Thus, there is no motivation within May or Massaro to combine the reference teachings to provide conjugate pad, or any other arrangement that allows for the reagent and analyte to mix prior to entry into test strip, and claims 1 and 13 are not obvious in light of these references.

Moreover, the instant method and device is highly sensitive and capable of reliably detecting Bence Jones proteins in low concentrations in untreated urine, as shown by Example 3 in the Application. Although Massaro is able to detect low concentrations of Bence Jones Proteins, Massaro teaches away from using methods having porous membranes with low sensitivity, see e.g. column 1, at line 40. Since Massaro teaches away from using porous membranes, such as electrophoresis, Massaro essentially teaches away from running samples through any porous medium when testing for Bence Jones proteins. The claimed invention however uses a porous membrane but unexpectedly achieves highly sensitive results, which are reliable, by utilizing a conjugate pad, and a test strip. See Example 3 in the Application. Accordingly, there would be no motivation within the reference teachings to combine Massaro with the device of May to achieve the objectives of using a porous medium and still achieving highly sensitive, and reliable methods and devices of claims 1 and 13.

Consequently, a combination of May and Massaro would create a completely different way than the claimed invention, by requiring pretreating urine through centrifugation and the addition of antiserum reagent directly to the liquid sample before being tested. In contrast, as described in paragraph 15 of the instant application, Applicant's invention teaches the use of untreated urine with conjugate pads. Thus, the combination of May and Massaro teach a different process than the objectives of the present invention of using untreated urine, and claims 1, and 13 are therefore, not obvious in light of May and Massaro.

The Examiner has maintained his obviousness objection based upon May, Massaro, and Brizgy. As stated above, May does not disclose a conjugate pad, and the conjugate pad of the claimed invention is a separate and different material than the chromatographic test strip, which performs a function not available by using the May device. The addition of Brizgy does not fill in the deficiencies noted against May and Massaro or suggest the advantages of using untreated urine as in the application to obtain highly sensitive, reliable results. Moreover, there is no disclosure or suggestion in Brizgy or Massaro to make the modifications in the May device, which would result in Applicants' device as claimed in claims 1, and 13.

Independent claim 26 is directed towards a test strip for the determination of an analyte in urine comprising, among other things, a chromatographic test strip, a first reaction site comprising a first immobilized specific binding reagent capable of immobilizing a chromogenic mobile specific binding partner bound to said analyte in the urine sample, wherein said analyte is selected from the group consisting of free light chains and classes thereof, which is not disclosed, taught or suggested by May, or Massaro.

Although, May does relate to chromatographic test strips for detecting proteins, nowhere does May suggest the use of test strips for detecting free light chains and classes thereof.

Further, Massaro fails to suggest using any test strip whatsoever, and teaches away from using any methods or strips that result in unacceptably low sensitivity and resulting unreliability. See Massaro column 1, line 40 where Massaro describes electrophoreses as a technique using porous medium which requires concentration of the sample because of the relatively small percentage of free light chains in the organic liquid even with serious pathological conditions of the subject. Massaro specifically teaches that electrophoretic examination of the sample results in unacceptably low sensitivity. See Massaro Column 1, lines 35 +. Since Massaro teaches away from using porous medium such as those used in electrophoresis, Massaro essentially teaches away from running samples through any porous medium when sensitivity, and reliability are a problem. The claimed invention achieves highly sensitive results, which are reliable. See Example 3 in Application. Accordingly, there would be no motivation within the reference teachings to combine Massaro with the device of May to achieve the objectives of being highly sensitive to free light chains and classes thereof, and claim 26 is not obvious.

The addition of Brizgy does make claim 26 obvious because it does not fill in the deficiencies noted against May and Massaro or suggest the advantages of using untreated urine, to obtain highly sensitive results. Moreover, there is no disclosure or suggestion in Brizgy or Massaro to make the modifications in the May device, which would result in Applicants' device as claimed in claim 26, accordingly the invention is not obvious.

The Examiner has cited Deutch for its teaching of a test tube for holding a liquid. The addition of Deutch does not fill in the deficiencies noted against May and Massaro, or Brizgy or suggest the advantages of using untreated urine, to obtain highly sensitive results. Moreover, there is no disclosure or suggestion in Deutch to make the modifications in the May device, which would result in Applicants' device as claimed in claims 26.

Because independent claims 1, 13, and 26 are not obvious, all of the claims that depend on claims 1, 13, and 26 remaining in the application, namely claims 2-12, 14-23, 25, 27-30 and 32-40 are in order for allowance, and early notice to that effect is respectfully requested.

The Examiner is invited to call Michael Krenicky at (203) 324-6155 if the Examiner has any questions about this invention or response.

Respectfully submitted,

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